From: POULSEN Mike

To: <u>Eric Blischke/R10/USEPA/US@EPA</u>

Cc: Chip Humphrey/R10/USEPA/US@EPA; Dana Davoli/R10/USEPA/US@EPA; danadavoli@avvanta.com; FARRER

David G

Subject: RE: Portland Harbor breast milk

Date: 04/07/2008 11:22 AM

Eric -

I've tried to address your questions below. I haven't proposed much revision to Dana's cover memo other than a statement along the lines of "give us a good reason why we shouldn't include this pathway, because we can't think of one."

- Mike

Cover memo does not really tee up the public policy issues.

I suggest we insert the following near the end of the first paragraph in Dana's cover memo: "We consider breast feeding to be an important exposure pathway, particularly for PCBs. Breast feeding has not been considered in most Superfund risk assessments, but we see no reason to exclude this pathway."

How are the benefits of breast feeding accounted for?

Benefits are not typically accounted for in risk assessments. For example, we do not present the benefits of eating fish. So we are not planning a risk-benefit analysis. However, benefits of breast feeding may be implicitly included if we use the ATSDR intermediate-duration MRL (instead of the chronic RfD). The MRL was developed during infant monkey exposure that would be consistent with the exposure period for a breast-feeding human infant.

What is the best way to present this information to the public in a non-alarmist way?

We acknowledge that the risk assessment will show potential risks associated with high fish consumption and associated bioaccumulation of PCBs in the mother's body. The risk calculations are supported by public health studies that show health effects associated with PCB concentrations in breast milk. Our previous preliminary risk assessment conclusion that there are potential health effects to adults from consumption of PCBs in fish is now expanded to include potential health effects to offspring, which may in fact be more important. This conclusion is already included in the existing fish advisory for the site. We are now providing quantitative support for the statement in the advisory, so we are not really saying anything new. However, we recognize that this information may dissuade mothers from breast feeding. For this reason we provide in the memo proposed text to be included by the LWG in the risk assessment regarding the benefits of breast feeding and the public health recommendation to continue breast feeding. There will also be a separate document by DHS (with ATSDR review) that can be referred to.

Is this information necessary for making remedial action decisions at the site?

Yes. This is an important pathway, and appears to be the risk driver for $\ensuremath{\mathsf{PCBs}}$.

And ultimately, what end result from assessing and presenting this scenario do we hope to achieve?

As with any important exposure pathway, we want to evaluate the associated risks and determine acceptable levels for cleanup. We cannot do this if we do not conduct a quantitative evaluation.

----Original Message---From: Blischke.Eric@epamail.epa.gov
[mailto:Blischke.Eric@epamail.epa.gov]
Sent: Monday, April 07, 2008 10:09 AM
To: POULSEN Mike
Cc: Humphrey.Chip@epamail.epa.gov; Davoli.Dana@epamail.epa.gov;
danadavoli@avvanta.com; FARRER David G
Subject: RE: Portland Harbor breast milk

Based on a quick review of the memo, I have no issues with the methodology as it is written up. It seems to be a comprehensive summary of the methodology and very well presented. However, I have concerns about the cover memo because it does not really tee up the public policy issues - namely, how are the benefits of breast feeding accounted for? What is the best way to present this information to the public in a non-alarmist way? Is this information necessary for making remedial action decisions at the site? And ultimately, what end result from assessing and presenting this scenario do we hope to achieve?

I will try to touch base with Dana on this. In the meantime, I will make an attempt to insert some language that gets at the concerns I outlined above; any thoughts are welcome.

Thanks, Eric

"POULSEN Mike" <POULSEN.Mike@de q.state.or.us>

04/07/2008 09:44

Eric Blischke/R10/USEPA/US@EPA, Chip Humphrey/R10/USEPA/US@EPA

<danadavoli@avvanta.com>, Dana
Davoli/R10/USEPA/US@EPA, "FARRER
David_G" <David.G.Farrer@state.or.us>

Subject RE: Portland Harbor breast milk

Chip & Eric -

I incorporated Dana's revisions in the main memo after making a few minor edits. I think this is in good shape to send out for EPA review. After your approval, of course. I didn't have any comments on the cover

----Original Message--

From: Davoli.Dana@epamail.epa.gov [mailto:Davoli.Dana@epamail.epa.gov]
Sent: Saturday, April 05, 2008 3:52 PM
To: POULSEN Mike; FARRER David G; Blischke.Eric@epamail.epa.gov;
Humphrey.Chi@epamail.epa.gov

danadavoli@avvanta.com

Subject: Re: Portland Harbor breast milk

(b) (6)

(marked up version and edits accepted version) and Mike's technical write-up (marked up only). For the memo to reviewers, I added Mike's comments and a few more statements/questions about the health consultation. For the technical document, I added some language from RAGs defining chronic exposure (Mike, could you please add the footnote correctly and add the the RAGs reference which is on the reference page to the list of references). I also made some edits so that the document is using 1 ppm for resident fish as an example (as opposed to bass). It seemed a bit easier to read and flows nicely into the statement that compares the 1ppm to bass and carp fish data in PH. I do not feel strongly about this so you guys can ignore the the changes if want to. I am hoping that Mike and Dave can look these over and get any final comments to Chip and Eric as early as possible on Monday. he EPA reviewers

Chip and Eric, I would like to have one of you send this to the Region 10 group (RPMs and risk assessors) that has been involved in the Puget Sound Tribal Seafood Consumption Framework. As I mentioned in yesterday's e-mail to you both, the group is meeting on Thursday afternoon (April 10) and I would like to have a brief discussion at the end of the meeting on this issue (hopefully with all of you on the phone). It would be great if one of you could send the reviewers' memo and tech document/consult to the group by Tuesday. It doesn't have to be perfect as I am sure we will get comments on it. This is the mail group:

Allison Hiltner/R10/USEPA/US@EPA, Charles Ordine/R10/USEPA/US@EPA Christy Brown/R10/USEPA/US@EPA, Dana Davoli/R10/USEPA/US@EPA, Eri Hoffman/R10/USEPA/US@EPA, Howard Orlean/R10/USEPA/US@EPA, Julius Nwosu/R10/USEPA/US@EPA, Lori Cohen/R10/USEPA/US@EPA, Marc NWOSU/RIO/USEPA/US@EPA, LOTI COMEN/RIO/USEPA/US@EPA, MARC Stifelman/RIO/USEPA/US@EPA, Marcia Bailey/RIO/USEPA/US@EPA, Michael Cox/RIO/USEPA/US@EPA, Nancy Harney/RIO/USEPA/US@EPA, Piper Peterson Lee/RIO/USEPA/US@EPA, Ravi Sanga/RIO/USEPA/US@EPA, Rich McAllister/RIO/USEPA/US@EPA, Rick Albright/RIO/USEPA/US@EPA, Shawn Blocker/RIO/USEPA/US@EPA, Sheila Eckman/RIO/USEPA/US@EPA, Lon Kissinger/R10/USEPA/US

Lon is in hearge of setting up the meetings and I have asked $\mathop{\text{\rm him}}\nolimits$ to add this topic.

(b) (6)

Also below is some language from the SSL guidance that I found interesting:

EPA Soil Screening Guidance: Technical Background Document http://www.epa.gov/superfund/health/conmedia/soil/introtbd.htm)

2.2 Direct Ingestion Calculation of SSLs for direct ingestion of soil is based on the $\,$ Calculation of SSLs for direct ingestion of soil is based on the methodology presented for residential land use in RAGS HHEM, Part B (U.S. EPA, 1991b). Briefly, this methodology backcalculates a soil concentration level from a target risk (for carcinogens) or hazard quotient (for noncarcinogens). A number of studies have shown that inadvertent ingestion of soil is common among children 6 years old and younger (Calabrese et al., 1989; Davis et al., 1990; Van Wijnen et al., 1990). Therefore, the approach uses an age-adjusted soil ingestion factor that takes into account the difference in daily soil ingestion rates, body weights, and exposure duration for children from 1 to 6 years old and others from 7 to 31 years old. The higher intake rate of soil by children and their lower body weights lead to a lower, or more conservative, risk-based concentration compared to an adult-only assumption. RAGS HHEM, Part B uses this age-adjusted approach for both noncarcinogens and carcinogens. For noncarcinogens, the definition of an RfD has led to debates concerning the comparison of lessthan-lifetime estimates of exposure to the RfD. Specifically, it is often asked whether the comparison of a 6-year exposure, estimated for children via soil ingestion, to the chronic RfD is unnecessarily conservative.

In their analysis of the issue, the SAB indicates that, for most chemicals, the approach of combining the higher 6-year exposure for children with chronic toxicity criteria is overly protective (U.S. EPA, 1993e). However, they noted that there are instances when the chronic RfD may be based on endpoints of toxicity that are specific to children (e.g., fluoride and nitrates) or when the doseresponse

nitrates) or when the doseresponse curve is steep (i.e., the dosage difference between the no-observed-adverse-effects level [NOAEL] and an adverse effects level is small). Thus, for the purposes of screening, OERR opted to base the generic SSLs for noncarcinogenic contaminants on the more conservative "childhood only" exposure (Equation 1). The issue of whether to maintain this more conservative approach throughout the baseline risk assessment and establishing remediation goals will depend on how the toxicology of the chemical relates to the issues raised by the SAB.

For noncarcinogens, averaging time is equal to exposure duration. Unlike RAGS HHEM, Part B, SSLs are calculated only for 6-year childhood exposure.

For carcinogens, both the magnitude and duration of exposure are important. Duration is critical because the toxicity criteria are based on "lifetime average daily dose." Therefore, the total dose received, whether it be over 5 years or 50 years, is averaged over a lifetime of 70 years. To be protective of exposures to carcinogens in the residential setting, RAGS HHEM, Part B (U.S. EPA, 1991b) and EPA focus on exposures to individuals who may live in the same residence for a "highend" period of time (e.g., 30 years). As mentioned above, exposure to soil is higher during childhood and decreases with age. Thus, Equation 2 uses the RAGS HHEM, Part B time-weighted average soil ingestion rate for children and adults; the derivation of this factor is shown in Equation 3.

(See attached file: 20080405 DAVOLI Final Draft of Letter to Reviewers.doc)(See attached file: 20080405 DAVOLI EDITS ACCEPTED Final Draft of Letter to Reviewers.doc)

(See attached file: 20080405 DAVOLI Final Draft Proposed Approach for Breastfeeding and Health Consultation .doc) (See attached file: 20080407 DAVOLI Final Draft Proposed Approach for Breastfeeding and Health Consultation.doc)